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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,558	03/19/2004	Rosa Cuberes Altiscn	785-011731-US (PAR)	7436

2512 7590 03/02/2006

PERMAN & GREEN  
425 POST ROAD  
FAIRFIELD, CT 06824

EXAMINER
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FREISTEIN, ANDREW B

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/804,558

Applicant(s)

CUBERES ALTISEN ET AL.

Examiner

Andrew B. Freistein

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 17, 18 and 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 15, 19 and 30 is/are rejected.
- 7) ☒ Claim(s) 1-16, 19 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2-02-06; 8-22-05; 11-02-04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-30 are currently pending in the instant application.

#### *Priority*

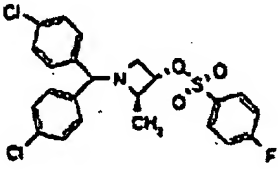
Acknowledgement is made of Applicant's claim for foreign priority under 35 U.S.C. § 119(a)-(d), by Spain patent application 2004 00379 filed on 02/17/2004.

#### *Information Disclosure Statement*

Applicant's information disclosure statements (IDSs), filed on 2/2/2006, 8/22/05 and 11/2/2004, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

#### *Restriction Requirement*

Acknowledgement is made of Applicant's election (with traverse) of Group I, claims 1-16, and the species 4-Fluoro-benzensulfonic acid 1-[trans-bis-(4-chloro-

phenyl)-methyl]-2-methyl-azetidin-3-yl ester, , in a response filed 2/02/2006.

Applicant traverses the restriction requirement between Group I and claim 19 of Group III. Claim 19 and newly added claim 30 are hereby rejoined into Group I. As a result, claims 1-16, 19 and 30 are now part of Group I.

#### *Status of the Claims*

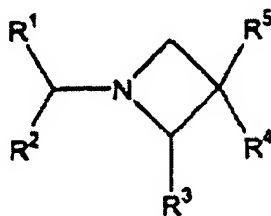
Claims 1-16, 19 & 30 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The

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withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



Compounds of the Formula I,

, wherein:

$R^1$  is as defined in claim 1;

$R^2$  is as defined in claim 1;

$R^3$  is a linear or branched, saturated or unsaturated, aliphatic group;

$R^4$  is H, a cyano group, a carboxy group, or linear or branched alkyl group;

$R^5$  is  $O-SO_2-R^6$ ,  $NHCO-R^7$ ,  $NH_2$ , or  $NH-SO_2-R^8$ ;

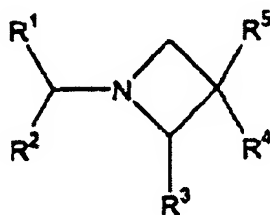
$R^6$  is linear or branched, saturated or unsaturated aliphatic group, a saturated or unsaturated cycloaliphatic group that does not contain a heteroatom;

$R^7$  is linear or branched, saturated or unsaturated aliphatic group, a saturated or unsaturated cycloaliphatic group that does not contain a heteroatom; and

$R^8$  is linear or branched, saturated or unsaturated aliphatic group, a saturated or unsaturated cycloaliphatic group that does not contain a heteroatom.

Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:



Compounds of the Formula I, , wherein:

R<sup>3</sup> is a cycloaliphatic group, which optionally contains a heteroatom, an optionally substituted aryl group, or a heteroaryl group;

R<sup>4</sup> is an optionally at least mono-substituted aryl group;

R<sup>5</sup> is NR<sup>9</sup>-SO<sub>2</sub>-R<sup>10</sup> or O-CO-R<sup>11</sup>;

R<sup>6</sup> is a saturated or unsaturated cycloaliphatic group that contains a heteroatom, an optionally at least mono-substituted aryl group, or heteroaryl group;

R<sup>7</sup> is a saturated or unsaturated cycloaliphatic group that contains a heteroatom, an optionally at least mono-substituted aryl group, or heteroaryl group; and

R<sup>8</sup> is a saturated or unsaturated cycloaliphatic group that contains a heteroatom, an optionally at least mono-substituted aryl group, or heteroaryl group.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 1-16, 19 and 30 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as thiazolidine, piperazine, quinoline, thiophene, morpholine, oxazol, pyrimidine, pyrazine, pyran, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

***Claim Rejections - 35 USC § 102***

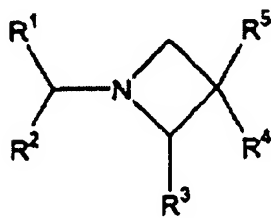
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

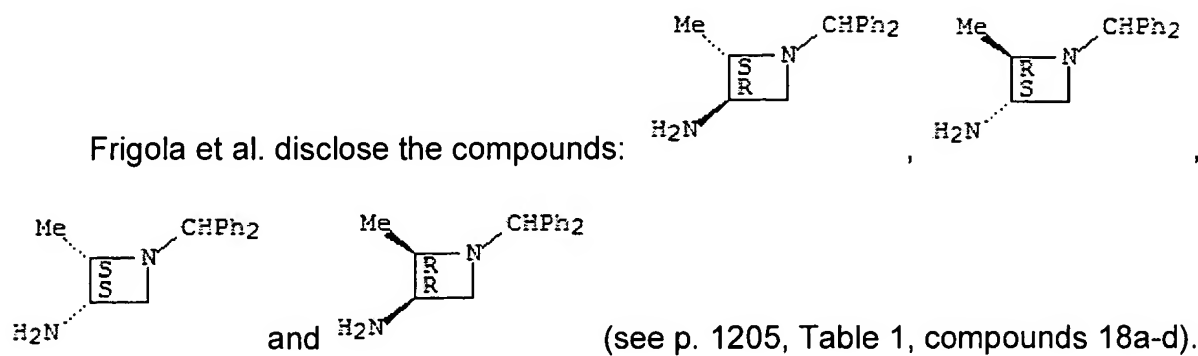
**(1) Claims 1-6, 15, 19 & 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Frigola et al, "7-Azetidinyloquinolones as Antibacterial Agents. 3. Synthesis, Properties and Structure-Activity Relationships of the Stereoisomers Containing a 7-(3-Amino-2-methyl-1-azetidinylo) Moiety," J. Med. Chem. 38(7) 1203-15 (1995).**

Claims 1-6 and 15 of the instant application are drawn to a compound of formula



(I), , wherein R<sup>1</sup> is phenyl; R<sup>2</sup> is phenyl; R<sup>3</sup> is an aliphatic group; R<sup>4</sup> is H; and R<sup>5</sup> is an NH<sub>2</sub> moiety.

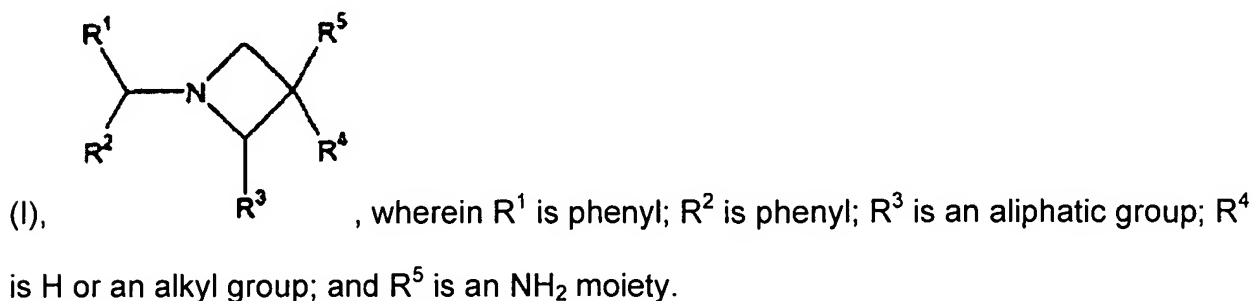
Claims 19 and 30 are drawn to a medicament comprising a compound of formula (I) and a pharmaceutically acceptable carrier.



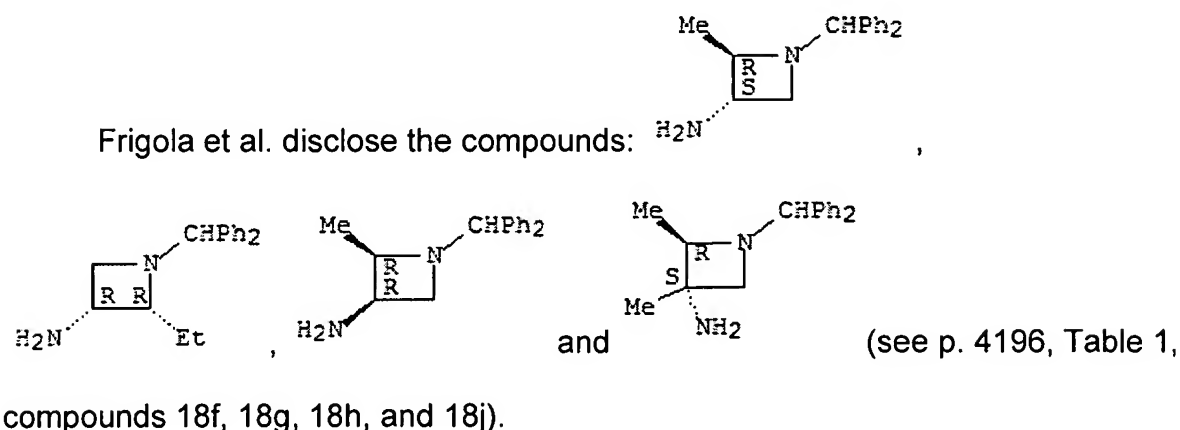
The compounds disclosed in Frigola et al. are disclosed for pharmacokinetic use. (see p. 1203, col. 1).

**(2) Claims 1-6, 15, 19 & 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Frigola et al., "7-Azetidinylnquinolones as Antibacterial Agents. 2. Synthesis and Biological Activity of 7-(2,3-Disubstituted-1-azetidiny)-4-oxoquinoline- and -1,8-naphthyridine-3-carboxylic Acids. Properties and Structure-Activity Relationships of Quinolones with an Azetidine Moiety," J. Med. Chem., 37(24), pp. 4195-210 (1994).**

Claims 1-6 and 15 of the instant application are drawn to a compound of formula



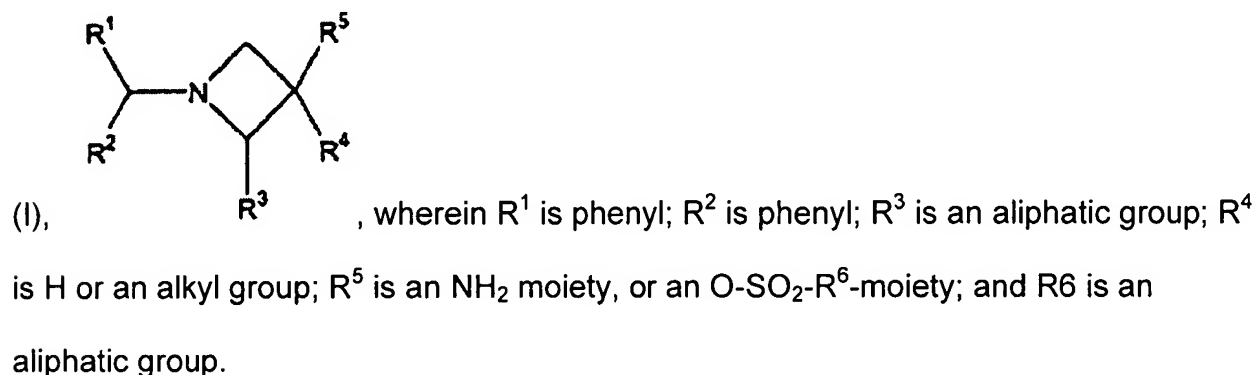
Claims 19 and 30 are drawn to a medicament comprising a compound of formula (I) and a pharmaceutically acceptable carrier.



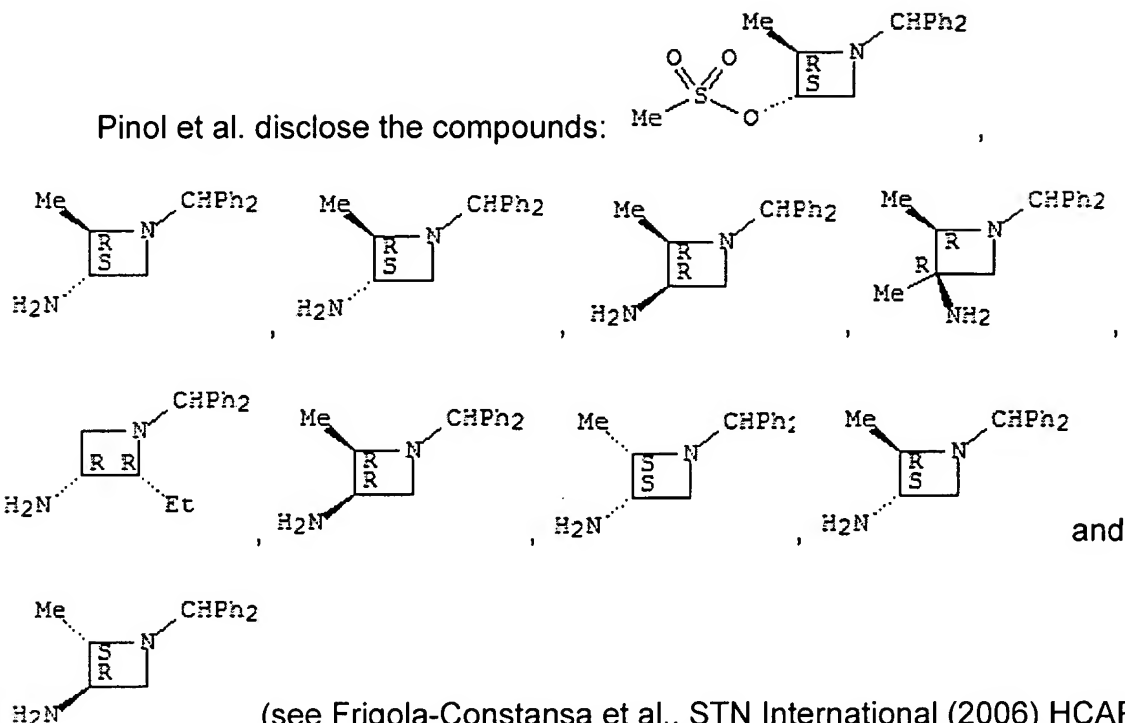
The compounds disclosed in Frigola et al. are disclosed for pharmacokinetic use. (see p. 4195, col. 1).

**(3) Claims 1-6 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinol et al., US Pat. No. 5,073,646.**

Claims 1-6 and 15 of the instant application are drawn to a compound of formula







(see Frigola-Constansa et al., STN International (2006) HCAPLUS

Database, Accession No. 1991:247111, Reg. Nos. 132924-39-1, 133891-54-0, 133891-55-1, 133891-67-5, 133891-68-6, 133891-71-1, 133963-10-7, 133963-11-8, 133963-12-9 and 133963-13-0.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

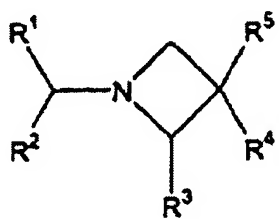
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 15, 19 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frigola et al., "7-Azetidinylnquinolones as Antibacterial Agents. 2. Synthesis and Biological Activity of 7-(2,3-Disubstituted-1-azetidiny)-4-oxoquinoline- and -1,8-naphthyridine-3-carboxylic Acids. Properties and Structure-Activity Relationships of Quinolones with an Azetidine Moiety," J. Med. Chem., 37(24), pp. 4195-210 (1994).

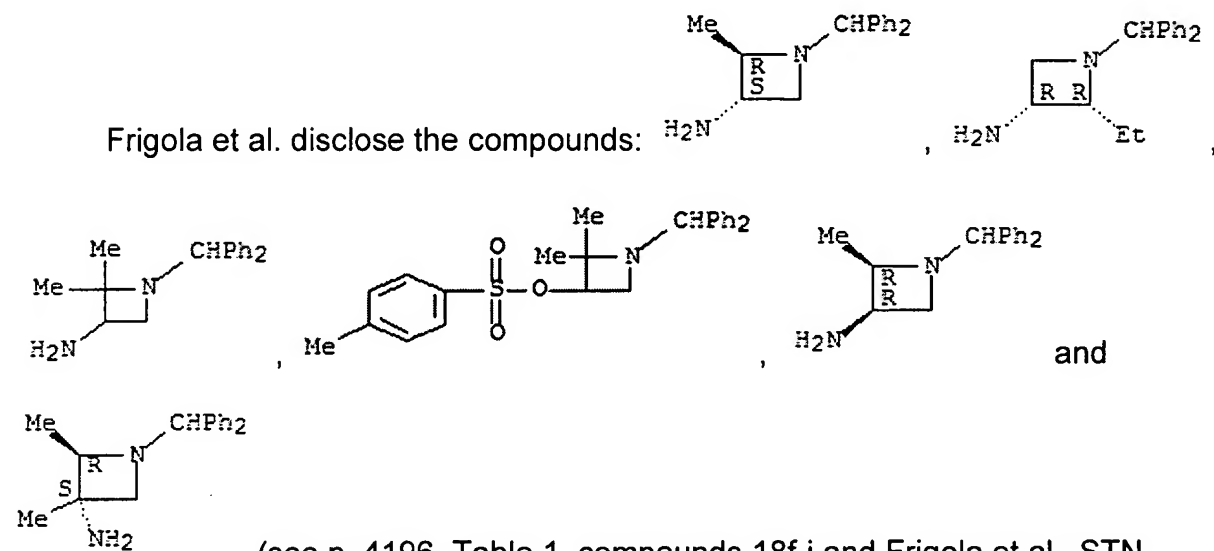
Claims 1-6, 9 and 15 of the instant application are drawn to a compound of



formula (I), , wherein R<sup>1</sup> is phenyl; R<sup>2</sup> is phenyl; R<sup>3</sup> is an aliphatic group; R<sup>4</sup> is H; R<sup>5</sup> is an NH<sub>2</sub> moiety, or an NH-SO<sub>2</sub>-R<sup>8</sup> moiety; R<sup>8</sup> is an optionally substituted 6-membered aryl group; with the exclusion of compounds wherein R<sup>1</sup> and R<sup>2</sup> are each unsubstituted phenyl, R<sup>5</sup> is O-SO<sub>2</sub>-R<sup>6</sup> and R<sup>6</sup> is methyl.

Claims 19 and 30 are drawn to a medicament comprising a compound of formula (I) and a pharmaceutically acceptable carrier.

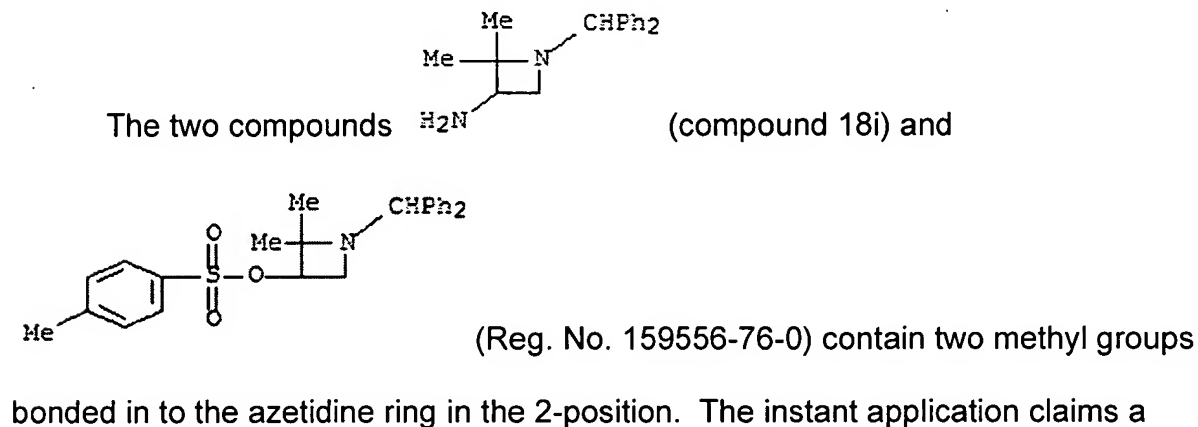
Determining the Scope and Content of the Prior Art



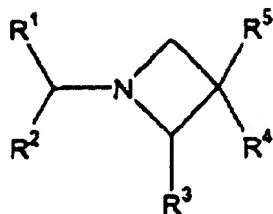
International, HCAPLUS (2006), Accession No. 1995:196535, Reg. No. 159556-76-0).

The compounds disclosed are used for antibacterial use and pharmacokinetic use (p. 4196, col. 1).

Ascertaining the Differences Between the Prior Art and the Instant Application



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compound of formula (I), , wherein R<sup>3</sup> is an aliphatic group, but the other substituent on this carbon is H. Thus the difference between these particular prior art species and the instant claims is hydrogen versus methyl.

Nevertheless, it is important to show that the prior art does provide species wherein R<sup>3</sup> is methyl and the other substituent is H (see p. 4196, Table 1, compound 18f, 18g and 18h).

#### *Finding Prima Facie Obviousness*

It is well established that the substitution of methyl for Hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 USPQ 137 (CCPA 1978) and *In re Lohr*, 137 USPQ 548, 549 (CCPA 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity. As a result, claims

#### ***Claim Objections***

Claims 1-16, 19 and 30 are objected to as being drawn to non-elected subject matter.

#### ***Telephone Inquiry***

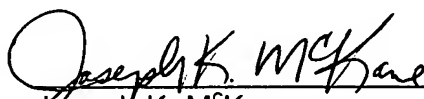
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein  
Patent Examiner, AU 1626

  
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Joseph K. M<sup>c</sup>Kane  
Supervisory Patent Examiner, AU 1626  
Date: February 27, 2006